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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,439	07/24/2003	Daniel P. Shevlin	074509.0102	9612

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EXAMINER

GRAY, PHILLIP A

ART UNIT	PAPER NUMBER
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3767

DATE MAILED: 10/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/626,439	Applicant(s) SHEVLIN, DANIEL P.	
	Examiner Phillip Gray	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 and 60-87 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-34 and 60-87 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to applicant's communication of 8/4/2006. Currently amended and newly added claims 1-34, and 60-87 are pending and stand rejected below.

Response to Arguments

Applicant's arguments filed 8/4/2006 have been fully considered but they are not persuasive. Applicants argue that Lattin does not anticipate the pending and newly added claims as written. Specifically applicant argues that Lattin does not disclose, teach, or suggest 1.) "a battery positioned between the first and second reservoirs", 2.) "a reservoir pad adapted to absorb the therapeutic agents to be delivered to the user" and 3.) "a foldable connecting portion".

Concerning the first argument by applicant (1.) It is examiners position that Lattin and the prior art of record does disclose "a battery positioned between the first and second reservoirs. Lattin discloses many embodiments where the battery would be considered "positioned between the first and second reservoirs". For instance in figure 12 element 512 is representative of the electronics, including the battery which is between the two reservoirs of that device (teaching that a battery may be placed between the two reservoirs). Further in figure 7 battery element 174 is shown between reservoirs near 172 and 176, which would be a teaching that the battery is placed between two reservoirs. Further still, as in another embodiment of figure 5, batteries that would be in element 120, would be considered positioned between reservoirs 24 and 23 (or "approximately midway"), when given the broadest reasonable interpretation

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of the word "between". During examination, claim limitations are to be given their broadest reasonable reading. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989); In re Prater, 415 F.2d 1393, 1404-1405, 162 USPQ 541, 550-51 (CCPA 1969).

Concerning the second argument by applicant (2.) It is examiners position that Lattin and the prior art of record disclose "a reservoir pad adapted to absorb the therapeutic agents to be delivered to the user". Examiner has pointed out elements 23 and 24, which contain a hydrophobic polymer or gel and used to store the medicament to be delivered. During examination, claim limitations are to be given their broadest reasonable reading. When given the broadest reasonable reading the term "pad" can mean "a cushion like mass of soft material used for comfort, protection, or stuffing" and these elements are reservoirs. Further element 20 around elements 23/24 would be considered the foam gasket. In response to applicant's argument that Lattin fails to teach that the pad is "adapted to absorb the therapeutic agents to be delivered", a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. It is examiners position that the reservoir pad of Lattin would be adapted to absorb therapeutic agents.

Concerning the third argument by applicant (3.) It is examiners position that Lattin and the prior art of record disclose "a foldable connecting portion". It is Lattin's element 202 that would be the foldable connecting portion (as one example). This

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folded and unfolded state is shown in figures 8 and 9. Examiner is unsure why applicant has argued that the accordion foldable connecting portion is not shown in a folded and unfolded state. Applicant's arguments concerning the foldable portion fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

For the above reasons the rejections stand and are proper.

Claim Objections

Claim 87 is objected to because of the following informalities: the claim does not distinctly claim and is ambiguous. The phrase "formed form different materials" is not limiting and is likely a typographical mistake. It is likely that applicant meant "from" instead of "form". Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-9, 11-16, 18-26, 28-33, 60-87 are rejected under 35 U.S.C. 102(e) as being anticipated by Lattin et al. (U.S. Patent Number 6,725,090). Lattin discloses a system, a method of use, and a method of manufacture, for iontophoretic transdermal delivery (see figures 1-13) of one or more therapeutic agents into a user's skin (see abstract and paragraphs at column 1-2), with a first end and first reservoir (23 or 24) for containing one or more therapeutic agents; a second end and second reservoir (24 or 27) for containing one or more therapeutic agents; and a connecting portion (202, 304, or 306) coupling the first end to the second end, the connecting portion housing: a self-contained power source (battery 37) for generating electric current, the power source comprising a first terminal and a second terminal (figures 3-11); at least a portion of a first electrode for electrically coupling the first terminal of the power source to the first reservoir (see paragraphs at column 11-12), the first electrode operable to conduct electric current between the power source and the first reservoir to ionize the one or more therapeutic agents contained within the first reservoir for iontophoretic transdermal

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delivery into the user's skin(figures 3-5); and at least a portion of a second electrode for electrically coupling the second terminal of the power source to the second reservoir, the second electrode operable to conduct electric current between the power source and the second reservoir to ionize the one or more therapeutic agents contained within the second reservoir for iontophoretic transdermal delivery into the user's skin (figure 13); the system adapted to be used in an extended or non-extended state (figure 9). Lattin discloses that the first and second reservoirs are adapted to deliver one or more therapeutic agents to one or more portions of a user's body substantially simultaneously (see paragraphs at columns 6-7). Lattin further discloses a device with a protective covering (32) associated with the connecting (20) portion and adapted to be removably coupled to a hypoallergenic adhesive on a bottom of the connecting portion, the hypoallergenic adhesive adapted to removably couple the system to a portion of the user's body. Lattin further discloses comprising a protective tab (16) associated with each reservoir, each tab adapted to be removably coupled to a hypoallergenic adhesive associated with its reservoir and further adapted to protect and provide protection from the therapeutic agents in its reservoir during application of the system to the user's skin, the hypoallergenic adhesive adapted to removably couple the system to a portion of the user's body (figures 1, 3-4). Lattin discloses that the first end is associated with a positive terminal of the power source and the second end is associated with a negative terminal of the power source (paragraphs at column 2-4). Lattin discloses each reservoir comprises: a reservoir pad adapted to absorb the therapeutic agents to be delivered to the user; and a reservoir gasket adapted to help contain the therapeutic agents

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contained in the reservoir pad (see figures 4,5,6) each comprising a soft, flexible, foldable, FDA-approved, hypoallergenic foam material (see paragraph at column 5-8). Lattin discloses that the power source comprise a flex-circuit and a hidden pocket disposed on the first or second end and adapted to house the connecting portion and at least a portion of the flex-circuit when the system is in the non-extended state (see figures 1b, 8-11). Lattin discloses a device that is fully capable to be disposable after a single use and that the power source is insulated in a protective covering made from a polymer or gel-like substance (see paragraphs at column 8 and element 506). Further Lattin discloses the first electrode, the second electrode, and the power source are disposed between at least one layer of insulating material to protect the user's skin (see figures 3-6 and paragraphs at column 7-10).

Concerning newly added claims, it is examiners position that the battery is positioned approximately midway between (see arguments above), the electrical system of electrodes are substantially flat and lie in the same plane and in a straight line (see figures 7,11,13), have the claimed gasket and pad (see arguments above) and the electrodes comprise a plurality of electrically conductive components formed of different materials (see columns 7-12 discussing circuitry).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lattin. Lattin does not specifically disclose a battery that is a 1.55 volt. It would have been obvious to have a 1.55 volt battery. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a 1.55 volt battery, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). In cases like the present, where patentability is said to be based upon particular chosen dimensions or upon another variable recited within the claims, applicant must show that the chosen dimensions are critical. As such, the claimed dimensions appear to be an obvious matter of engineering design choice and thus, while being a difference, does not serve in any way to patentably distinguish the claimed invention from the applied prior art. *In re Woodruff*, 919 F.2d 1575, 1578, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990); *In re Kuhle*, 526 F.2d 553, 555, 188 USPQ 7, 9 (CCPA 1975).

Claims 17 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lattin. Lattin discloses the claimed invention except for the system has a maximum thickness of approximately one-sixteenth of an inch. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the system having a maximum thickness of approximately one-sixteenth of an inch, since such a modification would have involved a mere change in the size of a

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component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gray whose telephone number is (571) 272-7180. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 4:30 p.m. EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

Kevin C. Sirmons